

## Ensifentrine Suspension Formulation

Version 1.1      Revision Date: 09.05.2026      SDS Number: 11619679-00002      Date of last issue: 07.01.2026  
Date of first issue: 07.01.2026

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### Section 1: Identification

**Product identifier** : Ensifentrine Suspension Formulation

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

#### Manufacturer or supplier's details

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

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### Section 2: Hazard identification

#### Classification of the substance or mixture

Not a hazardous substance or mixture.

#### GHS Label elements, including precautionary statements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### Other hazards which do not result in classification

None known.

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### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Ensifentrine	1884461-72-6	>= 0.1 -< 0.25

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### Section 4: First-aid measures

#### Description of necessary first-aid measures

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

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In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

### Most important symptoms and effects, both acute and delayed

Risks : None known.

Protection of first-aiders : No special precautions are necessary for first aid responders.

### Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## Section 5: Fire-fighting measures

### Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : No hazardous combustion products are known

### Special protective actions for fire-fighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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## Section 6: Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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### Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### Methods and materials for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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## Section 7: Handling and storage

### Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
Local/Total ventilation : Use only with adequate ventilation.  
Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.  
Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.  
Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

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### Section 8: Exposure controls/personal protection

#### Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ensifentrine	1884461-72-6	TWA	OEB 4 ( $\geq 1 < 10$ $\mu\text{g}/\text{m}^3$ )	Internal

**Appropriate engineering control measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

#### Individual protection measures, such as personal protective equipment (PPE)

**Eye/face protection** : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin protection** : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection** : No personal respiratory protective equipment normally required.

**Hand protection**

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Material : Chemical-resistant gloves  
Remarks : Consider double gloving.

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**Section 9: Physical and chemical properties**

Appearance : suspension  
Colour : light yellow, opaque  
Odour : No data available  
Odour Threshold : No data available  
pH : 6.7  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : No data available  
Flash point : No data available  
Evaporation rate : No data available  
Flammability (solid, gas) : Not applicable  
Flammability (liquids) : No data available  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available  
Vapour pressure : No data available  
Relative vapour density : No data available  
Relative density : No data available  
Density : No data available  
Solubility(ies)  
Water solubility : No data available  
Partition coefficient: n-octanol/water : Not applicable  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity  
Viscosity, kinematic : No data available

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Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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**Section 10: Stability and reactivity**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Ensifentrine:**

Species : Bovine cornea  
Result : No eye irritation  
Method : OECD Test Guideline 437

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Ensifentrine:**

Genotoxicity in vitro                   : Test Type: Ames test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo                   : Test Type: In vivo micronucleus test  
Species: Rat  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Ensifentrine:**

Species                                   : Rat  
Application Route                   : Inhalation  
Exposure time                       : 2 years  
NOAEL                                   : 7 mg/kg bw/day

**Reproductive toxicity**

Not classified based on available information.

**Components:****Ensifentrine:**

Effects on fertility                   : Test Type: Fertility  
Species: Rat  
Application Route: Inhalation  
Fertility: NOAEL: 6 mg/kg body weight  
Method: Study of Fertility and Early Embryonic Development to Implantation

Test Type: Fertility  
Species: Rat  
Application Route: Inhalation  
Fertility: LOAEL: 16 mg/kg body weight  
Target Organs: male reproductive organs  
Method: Study of Fertility and Early Embryonic Development to Implantation

Effects on foetal development   : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Inhalation  
Teratogenicity: NOAEL: 15 mg/kg body weight

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Test Type: Reproduction/Developmental toxicity screening test  
Species: Rabbit  
Application Route: Inhalation  
Teratogenicity: NOAEL: 12 mg/kg body weight

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Ensifentrine:**

Species : Dog  
NOAEL : 2 mg/kg  
LOAEL : 5.5 mg/kg  
Application Route : Inhalation  
Exposure time : 6 Weeks  
Number of exposures : BID  
Target Organs : Cardio-vascular system

Species : Dog  
LOAEL : 6 mg/kg  
Application Route : Inhalation  
Exposure time : 40 Weeks  
Target Organs : Cardio-vascular system

**Aspiration toxicity**

Not classified based on available information.

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**Section 12: Ecological information****Toxicity****Components:****Ensifentrine:**

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 0.65 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
EC10 (Raphidocelis subcapitata (freshwater green alga)): > 0.65 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.39 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.6 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 1000 mg/L  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Ensifentrine:**

Biodegradability : Method: OECD Test Guideline 301B  
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

**Bioaccumulative potential****Components:****Ensifentrine:**

Partition coefficient: n-octanol/water : log Pow: 3.19

**Mobility in soil****Components:****Ensifentrine:**

Distribution among environmental compartments : log Koc: 4.1 - 5.2  
Method: OECD Test Guideline 106

**Other adverse effects****Components:****Ensifentrine:**

Results of PBT and vPvB assessment : Remarks: Not classified due to lack of data.

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**Endocrine disrupting properties****Components:****Ensifentrine:**

Remarks : No data available

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**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**Section 14: Transport information****International Regulations****UNRTDG**

Not regulated as a dangerous good

UN number : Not applicable  
UN proper shipping name : Not applicable  
Transport hazard class(es) : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

**IATA-DGR**

Not regulated as a dangerous good

UN/ID No. : Not applicable  
UN proper shipping name : Not applicable  
Transport hazard class(es) : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

Not regulated as a dangerous good

UN number : Not applicable  
UN proper shipping name : Not applicable  
Transport hazard class(es) : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable  
Singapore Explosive Precursors (Guns, Explosives and Weapons Control Act, Second Schedule) : Not applicable  
Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

**The components of this product are reported in the following inventories:**

AICS : not determined  
CA. DSL : not determined  
CN IECSC : not determined

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**Section 16: Other information**

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**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

All - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International

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Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN